K010437

MAR 1 3 2001

Special 510(k) for the EBI XFIX® DFS® Rail System

1. 510(k) Summary of Safety and Effectiveness

A 510(k) Safety and Effectiveness Summary is provided as required by Section 513(I)3 of the Federal Food, Drug, and Cosmetic Act (510(k) summaries) and 21 CFR 807. EBI is using, where appropriate for the data submitted, the format outlined by the FDA in 21 CFR 807.92 (59 FR 64287, December 14, 1994). Appendix 1 contains the 510(k) summary for the EBI XFIX® DFS® Rail System and Appendix 3 contains Declarations of Conformity for Design Controls. This device is a Class II device, therefore, a Class III Certification is not applicable.

2. Intended Use

The EBI XFIX® DFS® Rail System is a single use, external fixation device. The product's intended use and fundamental scientific technology are the same as the previously cleared EBI XFIX® DFS® Rail System described in 510(k) numbers K991941 and K000083. Copies of the SE letters are included in Appendix 6.

The **EBI XFIX® DFS® Rail System** is a unilateral external fixation device intended for use in the treatment of bone conditions including limb lengthening, corrective osteotomies, arthrodesis, fracture fixation, acute or gradual multiplanar correction and other bone conditions amenable to treatment by use of the external fixation modality.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 3 2001

Ms. Patricia Flood, RAC
Regulatory Affairs Specialist
EBI, L.P.
100 Interpace Parkway
Parsippany, New Jersey 07054

Re: K010437
Trade Name: EBI XFIX® DFS® Rail System
Regulatory Class: Class II
Product Code: KTT
Dated: February 9, 2001
Received: February 13, 2001

Dear Ms. Flood:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

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510(k) Number (if known): K010437

Indications For Use:

The EBI XFIX® DFS® Rail System is a unilateral external fixation device intended for use in the treatment of bone conditions including limb lengthening, corrective osteotomies, arthrodesis, fracture fixation, acute or gradual multiplanar correction and other bone conditions amenable to treatment by use of the external fixation modality.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010437